

**From:** [Roark, Brian](#)  
**To:** [Sweet, Kara \(USATNM\)](#); [Robert S. Salcido \(rsalcido@akingump.com\)](#); [Sample, Taylor M.](#)  
**Cc:** [bryanvroon@gmail.com](#); [Jerry Martin](#); [Shuford, Wynn \(USATNM\)](#); [Chenery, Taylor](#); [Seth Hyatt](#); [Webber, Hannah E.](#)  
**Subject:** [EXTERNAL] RE: Conference re Evidentiary Motions  
**Date:** Wednesday, January 11, 2023 3:30:54 PM  
**Attachments:** [image001.png](#)

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Kara,

As to the first topic, we do not understand what you mean by “evidence relating to the safe harbors.” Which safe harbor(s)? Which element(s) of such safe harbors? For example, do you mean that Methodist would not be permitted to enter into evidence the fact of the parties having written affiliation agreements with a term of more than one year because those are elements of various safe harbors? Methodist will not enter into such a stipulation. You are correct that Methodist has not asserted any safe harbors as an affirmative defense. However, as explained fully in our motions to determine the sufficiency of the United States’ responses to Requests for Admission, evidence that may overlap with elements of various safe harbors is not relevant only when a defendant raises a safe harbor as an affirmative defense. It is also relevant to at least scienter and falsity, which the United States must prove. RFA 4, 7, and 8 have nothing to do with safe harbors. Proof of that is that none of our filings in our motions related to the Requests for Admission even reference safe harbors, but they do reference falsity and knowledge which are core issues in the litigation.

As to the second topic, Methodist has not taken the position that patient harm is an element of the AKS or that lack of patient harm can negate AKS liability that is otherwise proven. Again, as explained fully in our motions to determine the sufficiency of the United States’ responses to Requests for Admission, the fact that the United States has not identified any adverse patient outcomes is also relevant to at least scienter and falsity. The government in its Complaint and its Interrogatory responses puts directly at issue the level and sufficiency of service that West provided under the management services agreement. If, in fact, those management services were not comprehensive and robust, one would expect to see detrimental results as to the very vulnerable population that received these services. Instead, as you have seen in countless presentations, everyone saw precisely the opposite – that is, dramatically elevated cancer care throughout the community, evidencing that contrary to the government’s contention that inadequate, or incomplete, management services occurred, that precisely the opposite happened, that is, outstanding management services were provided, and, thus, everyone at Methodist had reason to believe that the management services agreement was fully, and expertly, performed, and not deficient. You also see how other courts have addressed this issue through our recent citation to the *Holland* case, which similarly rejected the government’s contention in an AKS case that inadequate management services were provided because of the government’s failure to cite proof that inadequate care was provided to the relevant patient population. (You, of course, have the burden of proof in this case, not Methodist.) Further, Methodist is not withholding any documents related to patient outcomes on which it intends to rely in its defense. The United States has not requested and Methodist has not produced individual patient records, but you are incorrect that Methodist has not produced any evidence concerning broader patient outcomes during Methodist’s affiliation with West. We will not enter into the proposed stipulation as we understand it.

We believe any motions in limine are premature. Methodist's defenses are clearly relevant to the allegations in the government's Complaint and, at trial, the court could not preclude this type of evidence until it, at a minimum, observed how the government sought to prove its case. Further, the United States is conflating discoverability under Rule 26, which is a low bar, with evidentiary standards intended to narrow issues for trial and protect a jury from objectionable evidence. Without a clearer understanding of the relief the United States is seeking in its motions in limine, Methodist is unable to take a position. We remain available to confer more fully by phone or in person.

Thanks.  
Brian

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**From:** Sweet, Kara (USATNM) <Kara.Sweet@usdoj.gov>  
**Sent:** Monday, January 9, 2023 12:41 PM  
**To:** Roark, Brian <BRoark@bassberry.com>; Robert S. Salcido (rsalcido@akingump.com) <rsalcido@akingump.com>; Sample, Taylor M. <taylor.sample@bassberry.com>  
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**Subject:** Conference re Evidentiary Motions

Brian,

When we submit our responses to your motion to deem the RFAs admitted, we intend to simultaneously file two motions *in limine* that detail the bases for our relevance objections. In accordance with our obligation to confer in advance of filing MILs, below is our position:

First, Methodist has not asserted a safe harbor as an affirmative defense in its Answer in this action. We intend to ask the Court to exclude evidence relating to the safe harbors, including any rules, regulations or guidance relating to the safe harbor. We do not intend to introduce such evidence, and Methodist should not be permitted to do so. Including evidence of the elements of a safe harbor when it is not an affirmative defense also would be confusing for a jury. Courts have excluded evidence of unasserted affirmative defenses, including the safe harbor. For the same reasons that this evidence should be excluded, the US should not be required to answer RFAs 4, 7 and 8, which relate to the safe harbors for the AKS that are not at issue in this action.

Second, patient outcomes from the relationship between Methodist and West are not relevant to any claim or defense in this action. We intend to ask the Court to exclude evidence of patient outcomes. It is not a defense to a violation of the AKS that patients were not harmed or that there were no adverse patient outcomes. Further, Rule 26 requires a party to produce the documents they intend to rely on in defense of an action. Methodist has not produced any evidence in this action concerning patient outcomes. Specifically, Methodist has not produced any patient records, let alone all patient records, as it seeks in RFAs 3 and 5, without any limitation to adult oncology

patients or even Medicare patients. Courts routinely exclude parties from introducing facts where such evidence has not been produced in discovery. For the same reasons that this evidence should be excluded, the US should not be required to answer RFAs 3 and 5.

Please let us know by Wednesday whether Methodist will stipulate that evidence of the AKS safe harbors and patient outcomes will not be introduced by any party on summary judgment or at the trial of this action. If Methodist will so stipulate, then Methodist also should withdraw its motions to determine the sufficiency of the US responses to the RFAs.

If Methodist does not agree to the above, then please confirm that the US can indicate that we conferred in advance of filing the motion and that you oppose the relief sought.

Kara



**Kara F. Sweet**  
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